

LAHIVE
&
COCKFIELD
LLP

COUNSELLORS AT LAW
28 STATE STREET
BOSTON, MASSACHUSETTS 02109-1784
TELEPHONE (617) 227-7400
FAX (617) 742-4214
lc@lahive.com

JOHN A. LAHIVE, JR. (1928-1997)
THOMAS V. SMURZYNSKI
RALPH A. LOREN
GIULIO A. DeCONTI, JR.
ANN LAMPORT HAMMITT
ELIZABETH A. HANLEY
AMY BAKER MANDRAGOURAS
ANTHONY A. LAURENTANO
KEVIN J. CANNING
JANE E. REMILLARD
DeANN FORAN SMITH
PETER C. LAURO
JEANNE M. DIGIORGIO
DEBRA J. MILASINIC, Ph.D.
DAVID J. RIKKERS
DAVID R. BURNS
JOHN S. CURRAN
SEAN D. DETWEILER

CYNTHIA L. KANIK, Ph.D.
MEGAN E. WILLIAMS, Ph.D.
RICHANAND
MICHAEL PHILLIPPS
LISA M. DIROCCO
HATHAWAY P. RUSSELL
MARIA LACCOTRIPE ZACHARAKIS, Ph.D.
VINCENT P. LOCCISANO
MERIDETH C. ARNOLD

SENIOR COUNSEL
JAMES E. COCKFIELD

OF COUNSEL
JEREMIAH LYNCH
WILLIAM A. SCOFIELD, JR.
SIBLEY P. REPPERT

PATENT AGENTS
THEODORE R. WEST
SHAYNE Y. HUFF, Ph.D.
DANIEL B. KO

TECHNICAL SPECIALISTS
CYNTHIA M. SOROOS
PETER W. DINI, Ph.D.
EUIHOON LEE
CATHERINE E. McPHERSON
ERIC F. WAGNER, Ph.D.
JACOB G. WEINTRAUB
JONATHAN M. SPARKS, Ph.D.
CRISTIN E. HOWLEY, Ph.D.

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September 9, 2002

Commissioner for Patents
Washington, D.C. 20231

Re: U.S. Patent Application Serial No. 09/781,133
Title: "Methods for Enhancing the Bioavailability of a Drug"
Inventors: Neil J. Hayward *et al.*
Filing Date: February 9, 2001
Attorney Docket No. PPI-064

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ORIGINALLY FILED

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

1. Response to Restriction Requirement Under 35 U.S.C. § 121;
2. Statement of Limited Recognition Under 37 C.F.R. §10.9(b); and
3. Pre-paid acknowledgment postcard.

Please charge any necessary fees to our Deposit Account No. 12-0080. The undersigned requests any extensions of time necessary to respond. *For this purpose, a duplicate of this sheet is enclosed.*

Certificate of First Class Mailing (37 CFR 1.8(a))

I hereby certify that this transmittal letter and the papers referred to as being enclosed therein are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on:

September 9, 2002

Date

Maria Laccotripe Zacharakis, Ph.D.
Limited Recognition Under 37 C.F.R. § 10.9(b)

LAHIVE & COCKFIELD, LLP

Attorneys at Law

By:

Maria Laccotripe Zacharakis, Ph.D.
Attorney for Applicants
Limited Recognition Under 37 C.F.R. §10.9(b)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Neil J. Hayward *et al.*

Serial No.: 09/781,133

Filed: February 9, 2001

FOR: "Methods for Enhancing the Bioavailability of
a Drug"

Attorney Docket No.: PPI-064

Group Art Unit: 1653

Examiner: J. E. Russel

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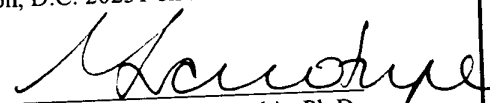
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Sept. 9, 2002
Date of Signature and of Mail Deposit

By:


Maria Laccotripe Zacharakis, Ph.D.
Limited Recognition Under 37 CFR §10.9(b)
Attorney for Applicants

RESPONSE TO RESTRICTION REQUIREMENT UNDER 35 U.S.C. §121

Dear Sir:

This is in response to the restriction requirement set forth in the Office Action dated August 9, 2002 (Paper No. 7).

The Examiner has required restriction to one of the following inventions under 35 U.S.C. §121:

- I. Claims 1-23, 42-46, and 49-52, drawn to a composition and method of enhancing the bioavailability of a drug by coadministration of a hydrophobic peptide, classified in class 514, subclass 17.

- II. Claims 24-32 and 47, drawn to a composition and method of enhancing the bioavailability of a β -amyloid peptide derivative to the brain by co-administering a P-glycoprotein inhibitor, classified in class 514, subclass 11.
- III. Claims 33-41 and 48, drawn to a composition and method of enhancing the bioavailability of a β -amyloid peptide derivative to the brain by co-administering a cytochrome P450 inhibitor, classified in class 514, subclass 17.
- IV. Claims 53-63, drawn to a method for treating or preventing hepatic injury or for modulating the levels of a hepatic enzyme by administering a P-glycoprotein inhibitor, classified in class 514, subclass 11.
- V. Claims 64-65, drawn to a composition and kit comprising a P-glycoprotein inhibitor and a drug for use in preventing hepatic injury, classified in class 514, subclass 11.

Applicants hereby elect Group II (claims 24-32 and 47) for prosecution *without traverse*.

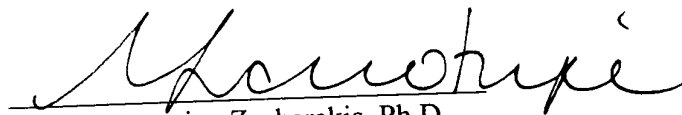
In addition, if Group I, II or III is elected, the Examiner has required the election of a β -amyloid peptide derivative recited in claims 3, 22, 25 and 34. Applicants hereby elect the β -amyloid peptide derivative PPI-1019.

It is the Applicants' understanding that under 35 U.S.C. §121, an election of a single species for prosecution on the merits is required, to which the claims will be restricted if no generic claim is finally held allowable. Applicants submit that claims 24, 25, 27-32 and 47 are generic. Applicants further understand that upon the allowance of a generic claim, they will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141.

SUMMARY

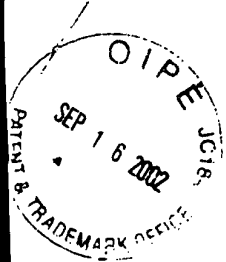
If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the examiner is urged to call Applicants' Attorney at (617) 227-7400.

Respectfully submitted,



Maria Laccotripe Zacharakis, Ph.D.
Limited Recognition Under 37 CFR §10.9(b)
Attorney for Applicants

LAHIVE & COCKFIELD
28 State Street
Boston, MA 02109
Tel. (617) 227-7400
Dated: September 9, 2002



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**BEFORE THE OFFICE OF ENROLLMENT AND DISCIPLINE
UNITED STATE PATENT AND TRADEMARK OFFICE**

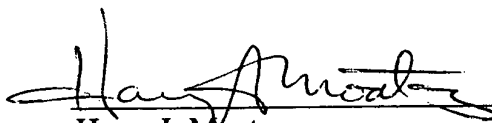
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LIMITED RECOGNITION UNDER 37 CFR § 10.9(b)

Maria C. Laccotripe Zacharakis is hereby given limited recognition under 37 CFR §10.9(b) as an employee of Lahive & Cockfield, LLP, to prepare and prosecute patent applications where the patent applicant is the client of Lahive & Cockfield, LLP, and the attorney or agent of record in the applications is a registered practitioner who is a member of the Lahive & Cockfield, LLP. This limited recognition shall expire on the date appearing below, or when whichever of the following events first occurs prior to the date appearing below: (i) Maria C. Laccotripe Zacharakis ceases to lawfully reside in the United States, (ii) Maria C. Laccotripe Zacharakis' employment with Lahive & Cockfield, LLP ceases or is terminated, or (iii) Maria C. Laccotripe Zacharakis ceases to remain or reside in the United States on an H-1 visa.

This document constitutes proof of such recognition. The original of this document is on file in the Office of Enrollment and Discipline of the U.S. Patent and Trademark Office.

Expires: August 5, 2003



Harry I. Moatz
Director of Enrollment and Discipline